[redacted] K030578

JUN 2 4 2003

510(k) Summary

Bipolar Grasper and Bipolar Scissors for the ZEUS® MicroWrist™ Surgical System

In accordance with 21 CFR section 807.92 Computer Motion is submitting the following 510(k) summary:

1) Submitter Information

Computer Motion. Inc.
130-B Cremona Drive
Goleta, CA 93117

Contact: Cathy Stupak, Ph.D.
Regulatory Specialist

2) Name of Device:

Proprietary Name:	Bipolar Grasper and Bipolar Scissors for the ZEUS® MicroWrist™ Surgical System
Common Name:	Bipolar Grasper and Bipolar Scissors
Classification Name:	System, Surgical, Computer Controlled Instrument
Regulation Number:	876.1500
Product Code:	NAY
Class:	Class II.

3) Substantial Equivalence:

This submission establishes the substantial equivalence of the ZEUS Bipolar Grasper and ZEUS Bipolar Scissors to the hand-held versions of these instruments:

- The Lyons™ Dissecting Forceps manufactured by Gyrus Medical, (K904993)
- The Evershears®, manufactured by Gyrus Medical, (K904993)

4) Description of the Device:

This premarket notification adds **a bipolar grasper and bipolar scissors** to the ZEUS® MicroWrist™ Surgical System. These surgical instruments are used in conjunction with an electrosurgical generator unit (ESU), and they augment the means of performing electrosurgical procedures with the ZEUS® MicroWrist™ Surgical System. These devices are additions to the MicroAssist™ line of ZEUS surgical instruments. MicroAssist instruments consist of commercially available hand-held devices that have been modified in order to be attached to the ZEUS arm. As with all MicroAssist instruments, the distal end that is used to perform surgical tasks remains unchanged from the hand-held version.

The ZEUS® MicroWrist™ Surgical System, consisting of a surgeon console and three table-mounted arms, serves as a platform for holding, positioning, and manipulating endoscopic instruments in order to perform selected surgical tasks. One arm of the ZEUS System incorporates the AESOP® endoscope positioner which provides the surgeon with a steady view of the internal operating field. The HERMES® O.R. Control Center, which uses voice-recognition technology to control devices outside the sterile field, is a standard component of the ZEUS System.

5) Intended Use

The Bipolar Grasper and Bipolar Scissors are surgical instruments used with the ZEUS® MicroWrist™ Surgical System. The Bipolar Grasper is intended to grasp, dissect, and coagulate tissue. The Bipolar Scissors provide mechanical cutting and bipolar coagulation. These bipolar instruments augment the means of performing electrosurgical procedures with the ZEUS® MicroWrist™ Surgical System.

6) Technological Characteristics in Comparison to the Predicates

The Bipolar Grasper and Bipolar Scissors, instruments for the ZEUS® MicroWrist™ Surgical System, are essentially identical in terms of size, shape, function, activation, and intended use to the predicate devices cited. The primary difference between the subject devices and the predicate devices is that the predicates are hand-held instruments while the subject devices are positioned and manipulated by the ZEUS® MicroWrist™ Surgical System.

7) Conclusion drawn from the Non-Clinical Tests

Data provided in this submission indicate that the basic functional characteristics of these devices are substantially equivalent to the predicates.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 24 2003

David Munjal, Ph.D.
Vice President, RA/QA/CA
Computer Motion, Inc.
130-B Cremona Drive
Santa Barbara, California 93117

Re: K030578
Trade/Device Name: Bipolar Grasper and Bipolar Scissors
for the ZEUS® Microwrist™ Surgical System
Regulation Number: 21 CFR 876.1500
Regulation Name: Computer controlled instrument surgical system
Regulatory Class: II
Product Code: NAY
Dated: May 28, 2003
Received: May 29, 2003

Dear Dr. Munjal:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

[redacted]

INDICATION FOR USE STATEMENT

510(k) Number (if known): K030578

Device Name: Bipolar Grasper and Bipolar Scissors for the ZEUS® MicroWrist™ Surgical System

The Bipolar Grasper and Bipolar Scissors are instruments used with the ZEUS® MicroWrist™ Surgical System. The Bipolar Grasper is intended to grasp, dissect, and coagulate tissue. The Bipolar Scissors provide mechanical cutting and bipolar coagulation. These bipolar instruments augment the means of performing electrosurgical procedures with the ZEUS® MicroWrist™ Surgical System.

(PLEASE NO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CRDH, Office of Device Evaluation (ODE)

Miriam C. Provost

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K030578

Prescription Use ✓ OR Over-the-Counter Use _____
(Per 21 CFR 801.109) (Optional Format 1-2-96)